

## REMARKS

This is a full and timely response to the Official Action mailed March 23, 2006. It is timely submitted in view of the Petition for Extension of Time submitted concurrently herewith. Reexamination and reconsideration of the rejections set forth therein in light of the following remarks are courteously requested.

Claims 25-30 have been added. They find basis in the Specification in original claims 1-6.

The Office Action of March 23, 2006 rejected Claims 1-24 under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 7,005,408. A Terminal Disclaimer in compliance with 37 CFR 1.321(c) has been filed concurrently herewith to overcome each non-statutory double patenting rejection.

The Office Action of March 23, 2006 rejected Claims 1-5 and 19-21 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,060,077 (Meignant) or U.S. Patent No. 4,347,237 (Evenstad et al.). In support of this rejection, the Office Action states on page 3, lines 3-4, "Meignant and Evenstad et al. disclose vaginal lubricating compositions comprising polyethylene glycol, preservatives and bioadhesives. Since polyethylene glycol is claimed as suitable in the instant claims, the compositions of the references are seen as inherently possessing applicants claimed temperature increase properties." Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants' claimed invention, as set forth in independent claims 1, 19, 20 and 21, relates to a substantially anhydrous lubricant composition containing at least one polyol and various methods of using such composition. Upon exposure to moisture, the claimed composition increases in temperature by at least about 5°C and which has a Maximum Energy Release Index of at least about 11 mJ/mg.

Applicants respectfully submit that Meignant relates to a galenical formulation for local hormonotherapy of vaginal dryness. Although the formulations described therein may contain polyoxyethylene glycol, they are also required to contain 17 $\beta$ -estradiol, a lipophilic agent such as a triglyceride as well as a hydrophilic gel-forming bioadhesive agent. Applicants respectfully submit that, in view of the presence of the lipophilic agent and 17 $\beta$ -estradiol, the compositions of Meignant will not increase in temperature upon exposure to moisture. The compositions of applicants' invention increase in temperature upon exposure to moisture because the ingredients therein associate with water in an exothermic reaction, generating a heat of hydration. The presence of a significant amount of lipophilic agent (See, for example, the compositions set forth in U.S. Patent No. 6,060,077 at col. 5, l. 40-50 and col. 6, l. 15-20) in association with a polyol

would prevent the formulation from associating with water upon exposure to moisture as the composition will be primarily hydrophobic. This is due to the fact that lipophilic agents, including surfactants triglycerides, estrogens and oils, do not generally exhibit the property of heat of solution or hydration, as they do not dissolve or hydrate in the presence of water. Furthermore, they tend to interfere with the reaction between polyhydric alcohols and water, which is responsible for warming in the type of system claimed in the above-captioned application. Thus, no heat of hydration will be generated and the compositions of applicants' invention would not have been anticipated by Meignant, either patently or inherently. Applicants therefore respectfully request reconsideration of the rejection under 35 U.S.C. 102(b) in view of Meignant.

Nor, applicants respectfully submit, does Evenstad et al. describe the compositions or methods of applicants' invention. Evenstad et al. relates to a solid lubricating suppository for coital use. The suppositories of Evenstad et al. contain a polyoxyalkylene polyol component, a non-ionic surfactant having an HLB value greater than 12 and a glyceride of an aliphatic carboxylic acid [Col. 2, l. 33-50]. Applicants respectfully submit that Evenstad et al. does not anticipate the compositions or methods of applicants' invention due to the presence of glyceride derivatives and surfactants within Evenstad's composition. Such ingredients as glycerides and surfactants would prevent the polyol components present in the Evenstad et al. compositions from becoming hydrated upon exposure to moisture, thus essentially preventing the generation of heat. Thus, Evenstad's compositions do not teach or suggest a composition in which a temperature increase will occur. Applicants therefore respectfully request reconsideration of the rejection under 35 U.S.C. 102(b) in view of Evenstad et al.

A document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim. Verdegall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Neither Meignant nor Evenstad et al. discloses, either explicitly or implicitly, individually or in combination the features of the compositions or methods set forth in independent claims 1, 19, 20 or 21. Thus, applicants respectfully submit that neither Meignant and Evenstad et al. can anticipate applicant' claimed inventions. Applicants therefore respectfully request reconsideration of the rejection of claims 1, 19, 20 and 21 under 35 U.S.C. 102(b).